

Patent  
Attorney's Docket No. 032405-058



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of )  
YENCHO, et al. ) Group Art Unit: 3762  
Continuation of Application No.: 09/132,711 ) Examiner: Bianco  
Filed: Herewith )  
For: METHOD AND SYSTEM FOR ATTACHING )  
A GRAFT TO A BLOOD VESSEL )

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination of the above-identified application, kindly amend the above-identified application as follows:

**IN THE CLAIMS:**

Kindly cancel Claims 1-29 prior to examination.

Please add new Claims 30-84 as follows:

30. An anastomosis device for connecting an end of a graft vessel to a side of a target vessel, the anastomosis device comprising:

a one-piece continuous body configured to expand from a reduced insertion configuration to an expanded configuration; and

a plurality of graft vessel penetrating elements attached to the body, wherein said elements are configured to penetrate the graft vessel without penetrating the target vessel.

31. The device of Claim 30, wherein the one-piece continuous body is formed of a superelastic or pseudoelastic material.

32. The device of Claim 31, wherein the one-piece continuous body is formed of NiTi alloy.

33. The device of Claim 31, wherein the one-piece continuous body is formed of stainless steel.

34. The device of Claim 30, wherein the body in the expanded configuration forms a flange at an interior of the target vessel wall.

35. The device of Claim 34, further comprising an outer flange.

36. The device of Claim 35, wherein said outer flange is connectable to the body.

37. An anastomosis device applicator for deploying an anastomosis device to connect a graft vessel to a target vessel, the applicator comprising:

    a first tube configured to receive an anastomosis device;

    a second tube concentric with the first tube, the first and second tubes configured for movement with respect to one another to deploy the anastomosis device; and

    a side hole in at least one of the first and second tubes configured to allow the graft vessel to pass out of the side of the tube.

38. The anastomosis applicator of Claim 37, wherein the second tube is rotatable with respect to the first tube.

39. The anastomosis applicator of Claim 37, wherein the second tube is translatable with respect to the first tube.

40. The anastomosis applicator of Claim 37, wherein the second tube is rotatable and translatable with respect to the first tube.

41. The anastomosis applicator of Claim 37, wherein the first tube is configured for removable connection to an anastomosis device.

42. The anastomosis applicator of Claim 37, further comprising a handle connected to the first and second tubes with a mechanism for deploying the anastomosis device.

43. The anastomosis applicator of Claim 37, in combination with an anastomosis device, wherein the first tube includes a plurality of connecting members at a distal end thereof and the anastomosis device includes a plurality of features arranged to removably connect to the plurality of connecting members.

44. The anastomosis applicator of Claim 37, in combination with an anastomosis device configured for connecting a graft vessel to a target vessel.

45. An anastomosis applicator for deploying an anastomosis device to connect a graft vessel to a target vessel, the applicator comprising:

a first tube configured to receive an anastomosis device, wherein said device comprises a distal end and a proximal end and a longitudinal axis;

a second tube concentric with the first tube, the first and second tubes configured for movement with respect to one another and configured for deployment of the anastomosis device; and

wherein the applicator has a pre-deployment configuration where at least one tube extends beyond the distal end of the device.

46. The anastomosis applicator of Claim 45, wherein the second tube is rotatable with respect to the first tube.

47. The anastomosis applicator of Claim 45, wherein the second tube is translatable with respect to the first tube.

48. The anastomosis applicator of Claim 45, wherein the second tube is rotatable and translatable with respect to the first tube.

49. The anastomosis applicator of Claim 45, in combination with an anastomosis device configured for connecting a graft vessel to a target vessel.

50. An anastomosis applicator for deploying an anastomosis device to connect a graft vessel to a target vessel, the applicator comprising:

a first tube configured to receive an anastomosis device;

a second tube concentric with the first tube, the first and second tubes configured for movement with respect to one another and configured for deployment of the anastomosis device;

a vessel penetrating member configured for incision of the target vessel; and

wherein the applicator is configured to maintain contact with the target vessel from the time of incision through complete deployment of the anastomosis device.

51. The anastomosis applicator of Claim 50, wherein the second tube is rotatable with respect to the first tube.

52. The anastomosis applicator of Claim 50, wherein the second tube is translatable with respect to the first tube.

53. The anastomosis applicator of Claim 50, wherein the second tube is rotatable and translatable with respect to the first tube.

54. The anastomosis applicator of Claim 50, in combination with an anastomosis device configured for connecting a graft vessel to a target vessel.

55. An anastomosis tool for use in connecting an end of a graft vessel to a side of a target vessel, the tool comprising a vessel penetrating member configured to penetrate the target vessel, wherein the tool is configured to penetrate the target vessel and deliver a one-piece anastomosis device to connect the graft vessel to the target vessel.

56. The anastomosis tool of Claim 55, wherein the anastomosis tool further comprises at least two concentric tubes configured for deploying the one-piece anastomosis device.

57. The anastomosis tool of Claim 55, wherein the concentric tubes are configured for movement with respect to one another to deploy the one-piece anastomosis device.

58. The anastomosis tool of Claim 56, wherein the vessel penetrating member is configured for positioning inside the concentric tubes.

Preliminary Amendment  
Continuation of Application No. 09/132,711  
Attorney Docket No. 032405-053

59. An integrated anastomosis tool for connecting an end of a graft vessel to a side of a target vessel, the tool comprising:
- a vessel penetrating member configured to penetrate the side of the target vessel;
  - a tubular anastomosis device configured to connect the end of the graft vessel to the side of the target vessel; and
  - an anastomosis device applicator for deploying the anastomosis device.

60. The tool of Claim 59, wherein the anastomosis device applicator includes two concentric tubes configured for movement with respect to one another and for the deployment of the anastomosis device.

61. The tool of Claim 59, wherein the tubular anastomosis device is a one-piece tubular anastomosis device.

62. The tool of Claim 59, wherein the tubular anastomosis device and anastomosis device applicator are configured for eversion of the end of the graft vessel over a distal or proximal end of the tubular anastomosis device.

63. The tool of Claim 62, wherein the tool is configured not to pass any portion of said tool through a lumen of said graft vessel.

64. The tool of Claim 59, wherein the vessel penetrating member is configured for positioning inside the anastomosis device applicator.

65. The tool of Claim 59, wherein the tubular anastomosis device is configured for insertion through an incision formed by the penetrating member.

Preliminary Amendment  
Continuation of Application No. 09/132,711  
Attorney Docket No. 032405-053

66. The tool of Claim 59, in combination with an anastomosis device configured for connecting a graft vessel to a target vessel.

67. An anastomosis device for connecting an end of a graft vessel to a side of a target vessel, the anastomosis device comprising:

a body having a longitudinal axis, an open proximal end, and an open distal end;

at least two deployable sections on the body, the deployable sections each having a pre-deployed configuration for insertion into the target vessel and a deployed configuration for connecting the graft vessel to the target vessel, wherein the anastomosis device is configured to collapse longitudinally when deployed.

68. The device of Claim 57, wherein the anastomosis device is configured to be longitudinally collapsed to a greater or lesser degree to position the deployable sections at a desired location.

69. A method of performing anastomosis between a graft vessel and a target vessel, the method comprising:

inserting an anastomosis device with a graft vessel connected thereto at least partly into a target vessel;

deploying a first flange of the anastomosis device within the target vessel;

moving the deployed first flange of the anastomosis device with the connected graft vessel into contact with an inner wall of the target vessel; and then

deploying a second flange of the anastomosis device outside of the target vessel.

70. The method of Claim 69, wherein the deploying step connects an end of the graft vessel to a side of the target vessel.

Preliminary Amendment  
Continuation of Application No. 09/132,711  
Attorney Docket No. 032405-053

71. The method of Claim 69, wherein the first flange and the second flange of the anastomosis device are deployed by an anastomosis device applicator.

72. The method of Claim 69, wherein the steps of deploying of the first flange and deploying the second flange are both performed by actuation of a handle of the anastomosis device applicator.

73. The method of Claim 72, wherein the actuation of the handle is performed manually.

74. The method of Claim 72, wherein the actuation of the handle is performed in a step wise manner.

75. The method of Claim 69, wherein the step of inserting the anastomosis device includes inserting a one-piece continuous ring anastomosis device.

76. The method of Claim 75, further comprising a step of evertting the graft vessel over at least a portion of the anastomosis device before inserting the anastomosis device.

77. A method of performing anastomosis between a graft vessel and a target vessel, the method comprising:

receiving an anastomosis device on an anastomosis device applicator having a vessel penetrating member;

connecting a graft vessel to the anastomosis device on the anastomosis device applicator;

penetrating a target vessel with the vessel penetrating member of the anastomosis device applicator;

Preliminary Amendment  
Continuation of Application No. 09/132,711  
Attorney Docket No. 032405-053

advancing the anastomosis device into the penetration in the target vessel;  
and

deploying the anastomosis device with the anastomosis device applicator to connect the graft vessel to the target vessel.

78. The method of Claim 77, wherein the step of deploying the anastomosis device is performed by moving two tubes of the anastomosis device applicator with respect to one another to deploy the anastomosis device.

79. The method of Claim 77, wherein the anastomosis device is a one-piece anastomosis device.

80. The method of Claim 77, wherein during the penetrating step the vessel penetrating member is positioned inside the anastomosis device applicator.

81. The method of Claim 77, wherein the step of deploying connects an end of the graft vessel to a side of the target vessel.

82. A method of performing anastomosis between a graft vessel and a target vessel, the method comprising:

receiving an anastomosis device on an anastomosis device applicator including a first tube and a second tube;

connecting a graft vessel to the anastomosis device on the anastomosis device applicator with an end of the graft vessel passing out a side hole of at least one of the first and second tubes; and

deploying the anastomosis device with the anastomosis device applicator to connect the graft vessel to the target vessel.

Preliminary Amendment  
Continuation of Application No. 09/132,711  
Attorney Docket No. 032405-053

83. The method of Claim 82, wherein the step of deploying the anastomosis device is performed by moving the first and second tubes with respect to one another.

84. The method of Claim 82, wherein the step of receiving the anastomosis device on the anastomosis device applicator is performed by removably connecting a plurality of features of the anastomosis device to a plurality of connecting members at a distal end of the first tube.

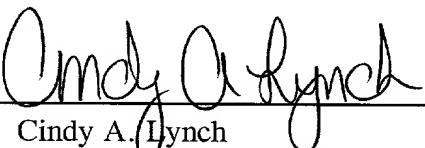
**REMARKS**

This Preliminary Amendment has been made to add new claims further defining the protection to which Applicants are entitled.

In the event that there are any questions concerning this Amendment, or the application in general, the Examiner is invited to contact the undersigned so as to expedite prosecution.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:   
Cindy A. Lynch  
Registration No. 38,699

Post Office Box 1404  
Alexandria, Virginia 22313-1404  
(650) 622-2300

Date: August 9, 2001